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EXAMINER

OGUNBIYI, OLUWATOSIN A

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

12/04/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

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The amendment filed 11/18/09 has been entered.

Rejections Withdrawn

The rejection of claims 18-23, 49 and newly added claims 64-78 rejected under 35 U.S.C. 112, first paragraph (scope of enablement) is withdrawn in view of the amendment to replace "vaccine" with immunogenic composition.

The objection to claims 71-72 under 37 CFR 1.75 as being a substantial duplicate of claim 70 is withdrawn in view of the amendment to the claims.

The objection to claim 80 under 37 CFR 1.75 as being a substantial duplicate of claim 6 is withdrawn in view of the cancellation of claim 80.

The rejection of claims 1, 4, 6, 7, 9-16, 18-23, 49 and 61-82 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendment to the claims.

The rejection of claims 79-82 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims to remove "consisting essentially of".

The rejection of claim 80 under 35 U.S.C. 112, first paragraph (scope of enablement) is withdrawn in view of the cancellation of the claim.

The rejection of claims 66, 69 and 78 under 35 U.S.C. 112, second paragraph is withdrawn in view of the cancellation of the claims.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 79 and 81-82 under 35 U.S.C. 112, first paragraph (scope of

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enablement) is maintained.

Applicants' arguments:

During the telephone interview (11/4/09) it was agreed that the specification did enable the claimed variant polypeptides, by providing preferred conserved amino acid exchanges (substitutions). These are found in the specification at page 26, lines 14-22, and are also recited by claim 82. It is submitted that the ordinary artisan, who has read the instant patent application, will be able to prepare a polypeptide according to claim 79 and 81-82 without undue experimentation.

Response:

Applicants' arguments have been carefully considered. Enablement rejection was discussed in view of these terms as the definition of "consisting essentially of" included that the polypeptide maintains characteristic of the polypeptide e.g. antigenicity of at least one epitope" and that the specification does not teach the epitopes of the instantly claimed proteins. It was agreed that removal of "consisting essentially of" would overcome the written description rejection. As to the enablement rejection, apparently it was not clearly communicated that although the specification is enabling for making the variant proteins, the specification has not enabled the use of the instant protein variants. It is noted that these issues as to the "use" prong of 35 USC 112, 1st paragraph were first raised in the previous Office Action 11/18/08 addressing claims to proteins comprising at least one conservative amino acid substitution and proteins that comprise at least 95% of the amino acid sequence (see claim 1, 54 and 55 in the claim set of 10/24/2008) and the rejected claims were amended or cancelled but the new claims of 8/18/09 presented the same issue. While, the specification is enabling for making the instant proteins, the specification is not enabling for the disclosed uses of variants of SEQ ID NO: 2 or 4 including those that are as a result of conservative amino acid substitution, as set forth in the previous rejection in the Office Action dated 8/18/09.

Status of claims

Claims 1, 4, 6-7,9-16, 18-23, 49, 61-65, 67-68, 70-71, 73-77 are allowable. Claims 79 and 81-82 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Oluwatosin Ogunbiyi/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645